America's Blood Centers

OUR MEMBERS SERVE COMMUNITIES NATIONWIDE

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Dockets Management Branch (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852.

Re: Docket No. 97D–0318: Guidance for Industry: Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products

Dear Docket Officer:

America's Blood Centers (ABC) is pleased to comment on FDA's recent guidance entitled *Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products*. For your information, ABC represents independent, FDA-licensed community blood centers that draw, process and distribute nearly half the volunteer blood supply in this country. Our members range in size from the very small community blood center with an annual draw of 10,000 to much larger establishments processing close to 1,000,000 units per year.

The members of America's Blood Centers are prepared to implement any deferral policies that FDA mandates in the name of blood safety. We remind FDA that adequacy of the blood supply is a safety issue.

We strongly request deletion of the question "Since 1980, have you knowingly obtained and been injected with a non U.S. licensed drug product made from cattle, such as bovine (beef) insulin?" until the issue can be subject to discussion in an open forum.

The information requested is obscure to the point of confusion, and blood collection facilities will be faced with making judgements about equivocal responses from donors with no resource for their resolution.

FDA did not solicit public discussion and industry comment of the rationale for this deferral criteria before its publication, and its impact on blood safety is unknown. Because this issue was not discussed at any public meeting of the Transmissible Spongiform Encephalopathy Advisory Committee Meeting or the Blood Products Advisory Committee, there has been no previous opportunity to make our concerns known.

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Given the entirely theoretical defense of any deferral related to nvCJD, the lack (to our knowledge) of a recognized association of nvCJD with such injections in endemic countries, the absence of an association with transfusion of nvCJD in epidemiologic studies, and the lack of TSE models suggesting transfusion transmission of other prions, deleting this deferral criteria until public discussion can take place about its merits will not unduly compromise the safety of the blood supply.

We believe that collection facilities should be given the option of providing prospective donors with a written "definition" of the United Kingdom prior to screening with a generic UK question.

The proposed language for Question 1: "Have you visited in or lived in the UK (England, Northern Ireland, Scotland, Wales, the Isle of Man, or the Channel Islands) from 1980 through 1996?" makes the question very long, both to print and to read. There are other methods for providing that information such as posted signs, or through provision of that information in the educational material which is given to donors prior to the screening interview.

We request that the AABB Uniform Donor History Questionnaire be permitted to continue to use the current terminology (which previously was approved by FDA): "Have you received a dura mater (brain covering) graft?"

The guidance proposes the lead-in question "Have you ever had brain surgery?" This question is significantly broader, will increase the time necessary to screen donors, and require additional documentation on the part of the donor interviewer when the initial answer is yes.

This question also fails to include an inquiry about spinal surgery, in which dura mater is sometimes used. We do not suggest that the question should include asking about spinal surgery for the same reason we do not ask about brain surgery. Asking a more direct question about dura mater will elicit the necessary information without adding confusion about other types of brain and/or spinal surgery.

While we remain highly skeptical of a blood safety increment from the recommendation for geographic deferral related to cumulative residence in the United Kingdom, we are aware of the precautionary principle justifying its implementation. We implore FDA to begin a public discussion of under what circumstances this deferral will be rescinded.

At a time when regional shortages are widespread and increasing, and the adequacy of national supply is uncertain, the nvCJD deferrals will reduce the blood supply by an estimated 2.2 percent. This represents 250,000 to 300,000 donors. Early anecdotal experience with this deferral in some centers that have implemented the ban suggests that these deferrals will be biased toward more frequent repeat donors than the average, so the impact will likely be greater in donations per year. The donors deferred by this action are among our most loyal and safe. Even if this action is reversed in the future, we know from

past history that it is very difficult to encourage donors to come back once they have been deferred.

Recruitment of new first time donors will be required, raising the issue of increasing the potential number of window period donations. We hope some will be interdicted by HCV and HIV NAT. For the HBV window, there is no comparable additional screen.

We continue to oppose the indefinite lookback requirements for components from volunteer whole blood donors having a single family member with classical CJD.

There is no epidemiological evidence of transfusion transmission and animal models of TSE transmission by blood suggest that infectivity is present in blood only in the late phases of the incubation period or during symptomatic disease. There is no clear message to the recipients of such blood components and there is no possible intervention. We believe that lookback in these cases serves no purpose and is counterproductive.

It would also be helpful if a flow chart summarizing required actions were provided in the final guidance document.

Thank you for the opportunity to comment. I would be please to answer any questions you might have about our comments.

Yours Truly,

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